We claim:

1. A pharmaceutical pellet comprising a substantially homogenous mixture of a rapidly-acting hypnotic agent or a pharmaceutically acceptable salt thereof and a pellet forming carrier wherein said pellet exhibits a dissolution profile under US Pharmacopoeia XXIII, Dissolution method I, in a basket apparatus at temperature 37°C, in 0.01N HCl medium and at 100 r.p.m., that includes 60% of the hypnotic agent being released from the pellet not earlier than 5 minutes from the start of the test.

2. The pellet according to claim 1, wherein said dissolution profile includes essentially 100% of the hypnotic agent being released from the pellet not earlier than 60 minutes from the start of the dissolution test.

3. The pellet according to claim 1, wherein said profile includes 80% of the hypnotic agent being released not earlier than 10 minutes from the start of the dissolution test.

4. The pellet according to claim 1, wherein said profile includes 85% of the hypnotic agent being released not earlier than 15 minutes from the start of the dissolution test.

5. The pellet according to claim 4, wherein said profile includes 70% of the hypnotic agent being released not earlier than 15 minutes from the start of the dissolution test.

6. The pellet according to claim 5, wherein said profile includes 50% of the hypnotic agent being released not earlier than 15 minutes from the start of the dissolution test.

7. The pellet according to claim 6, wherein said profile includes 40% of the hypnotic agent being released not earlier than 15 minutes from the start of the dissolution test.

8. The pellet according to claim 4, wherein said profile includes essentially 100% of the hypnotic agent being released within the range of 1 to 5 hours from the start of the dissolution test.

9. The pellet according to claim 8, wherein said profile includes essentially 100% of the hypnotic agent being released within the range of 2 to 4 hours from the start of the dissolution test.

10. The pellet according to claim 5, wherein said profile includes essentially 100% of the hypnotic agent being released within the range of 1 to 5 hours from the start of the dissolution test.

11. The pellet according to claim 1, wherein said hypnotic agent is selected from the group consisting of zolpidem, zopiclon, zaleplon, and benzodiazepines.

12. The pellet according to claim 2, wherein said hypnotic agent is selected from the group consisting of zolpidem, zopiclon, and zaleplon.

13. The pellet according to claim 4, wherein said hypnotic agent or pharmaceutically acceptable salt thereof is selected from the group consisting of zolpidem, zolpidem hydrochloride, zolpidem hydrochloride monohydrate, zolpidem hydrochloride ethanolate, zolpidem methane sulfonate, zolpidem tosylate, zolpidem maleate, zolpidem hydrobromide, zolpidem fumarate, zolpidem sulfate, zolpidem tartrate and zolpidem hydrogen tartrate.

14. The pellet according to claim 1, wherein said pellet does not contain a release rate controlling excipient or coating.

15. The pellet according to claim 1, wherein said pellet is monolithic.

16. The pellet according to claim 15, wherein said pellet does not contain a surface coating.

17. The pellet according to claim 1, wherein said pellet forming carrier is microcrystalline cellulose.

18. The pellet according to claim 6, wherein said pellet does not contain a release rate controlling excipient or coating.

19. The pellet according to claim 18, wherein said pellet is monolithic.

20. The pellet according to claim 19, wherein said pellet does not contain a surface coating.

21. The pellet according to claim 20, wherein said pellet forming carrier is microcrystalline cellulose.

22. The pellet according to claim 1, wherein said pellet does not contain a disintegrant.

23. The pellet according to claim 1, wherein said pellet contains from about 1 to about 50% by weight of said hypnotic agent.

24. The pellet according to claim 2, wherein said pellet contains from about 5 to about 50% by weight of zolpidem.

25. The pellet according to claim 24, wherein said pellet-forming carrier is a microcrystalline cellulose and the total amount of zolpidem and the carrier is at least 90% of the pellet weight.

26. A pharmaceutical unit dosage form, comprising an effective amount of the pellets according to claim 1.

27. The dosage form according to claim 26, wherein said dosage form contains from about 1 to about 50 mg of said hypnotic agent, expressed in terms of the free base.

28. The dosage form according to claim 27, wherein said dosage form contains from about 2.5 to about 50 mg of said hypnotic agent, expressed in terms of the free base.

29. The dosage form according to claim 26, wherein said unit dosage form is a capsule or tablet.

30. The dosage form according to claim 29, wherein said unit dosage form is a capsule filled with said pellets.

31. The dosage form according to claim 30, wherein said pellets have a particle size within the range of 0.85 to 1.7 mm.

32. The dosage from according to claim 31, wherein said pellets have a particle size of 1.4 to 1.7 mm.

33. The dosage form according to claim 28, wherein said dosage form contains 4 mg of zolpidem as said hypnotic agent and said dosage form exhibits a dissolution profile under US Pharmacopoeia XXIII, Dissolution method I, in a basket apparatus at temperature 37°C, in 0.01N HCl medium and at 100 r.p.m., such that at 15 minutes from the start of the dissolution test 3 mg or less of zolpidem is released.

34. The dosage form according to claim 28, wherein said dosage form contains 18 mg of zolpidem as said hypnotic agent and said dosage form exhibits a dissolution profile under US Pharmacopoeia XXIII, Dissolution method I, in a basket apparatus at temperature 37°C, in 0.01N HCl medium and at 100 r.p.m., such that at 15 minutes from the start of the dissolution test 6 mg or less of zolpidem is released.

35. The dosage form according to claim 34, wherein said 8 mg of zolpidem is in the form of zolpidem hydrogentartrate, expressed in terms of the free base.

36. The dosage form according to claim 34, wherein said release profile is such that at 15 minutes from the start of the dissolution test 5 mg or less of zolpidem is released and essentially 8 mg of zolpidem is released 5 hours or less from the start of the dissolution test.

37. The dosage form according to claim 36, wherein said pellets are spherical and monolithic.

38. A method of inducing or maintaining sleep, which comprises administering an effective hypnotic amount of the pellets according to claim 1 to a mammal.

39. The method according to claim 38, wherein said hypnotic agent is zolpidem free base or zolpidem hydrogen tartrate.

40. A pharmaceutically acceptable monolithic spherical pellet comprising microcrystalline cellulose and zolpidem or a pharmaceutically acceptable salt thereof, wherein said pellet does not contain a release rate controlling excipient or coating, does not contain a surface coating, and exhibits a dissolution profile under US Pharmacopoeia XXIII, Dissolution method I, in a basket apparatus at temperature 37°C, in 0.01N HCl medium and at 100 r.p.m., that includes 70 % of said zolpidem being released from the pellet not earlier than 15 minutes from the start of the dissolution test.

41. A process for making pharmaceutically acceptable spherical pellets, which comprises:
(1) combining a solvent, a pharmaceutically active agent and/or its pharmaceutically acceptable salt, and at least one pellet forming carrier to form a wet mixture, wherein the solvent is not combined by spraying;
(2) stirring, chopping, or both, the wet mixture to form monolithic, spherical wet pellets; and
(3) drying said wet pellets to form said pharmaceutically acceptable pellets.

42. The process according to claim 41, wherein said solvent is water.

43. The process according to claim 42, wherein said combining step comprises dumping water onto a homogenous dry blend of pharmaceutically active agent and/or its pharmaceutically acceptable salt and at least one pellet forming carrier to form said wet mixture.

44. The process according to claim 43, wherein said dumping of water comprises adding water at a rate within the range of 1 to 1200 seconds per liter.

45. The process according to claim 44, wherein said rate is within the range of 20 to 120 seconds per liter.

46. The process according to claim 43, wherein additional water is dumped onto said wet mixture during said stirring or chopping step (2).

47. The process according to claim 41, wherein said stirring or chopping step (2) comprises a total of 1 to 60 minutes of stirring, chopping, or combination thereof.

48. The process according to claim 47, wherein said stirring or chopping step (2) comprises a total of 5 to 20 minutes of stirring, chopping, or combination thereof.

49. The process according to claim 41, wherein said drying is carried out by heating, applying microwave or infrared energy, applying vacuum or reduced pressure, passing an inert gas over the wet pellets, or a combination thereof.

50. The process according to claim 49, wherein said drying step comprises heating under reduced pressure while passing nitrogen gas over said wet pellets and applying microwave energy.

51. The process according to claim 41, wherein said pellet forming carrier is microcrystalline cellulose.

52. The process according to claim 51, wherein said pharmaceutically active agent is selected from the group consisting of acarbose, alprostadil, amlodipine, artemotil, atorvastatine, benzodiazepines, citalopram, cladribine, clopidrogel, candesartan, carvedilol, desogestrel, dexrazoxane, diltiazem, dofetilide, donepezil, eprosartan, etanercept, etidronate, exemestane, latanoprost, leflunomide, letrozole, lovastatin, mirtazepine, modafinil, nateglinide, nimesulide, nizatidine, olanzapine, olopatidine, orlistat, oxybutynin, pramipexol, paroxetine, pioglitazone,

quetiapine, reboxetine, remoxepride, repaglinide, risperidon, rizatriptan, ropinirol, rosiglitazone, simvastatin, tamsulosin, telmisartan, tibolon, thalidomide, tolterodine, venlafaxine, zaleplon, ziprasidone, zolpidem, zonisamide, zopiclon, and pharmaceutically acceptable salts thereof.

53. The process according to claim 51, wherein said pharmaceutically active agent is a rapidly acting hypnotic.

54. The process according to claim 53, wherein said hypnotic agent is contained in an amount of from 1 to 50 % by weight and together said hypnotic agent and said microcrystalline cellulose account for at least 90 % of said pellets weight.

55. The process according to claim 54, wherein said hypnotic agent is zolpidem free base or zolpidem hydrogentartrate.

56. The pellet made by the process of claim 54.

57. The pellet made by the process of claim 45.